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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,408	12/26/2001	Larry Caldwell	CALD-005	3760

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EXAMINER
VU, JAKE MINH

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
12/09/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/029,408	CALDWELL ET AL.	
	Examiner	Art Unit	
	JAKE M. VU	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5-7,10,11,14-18,24-30 and 32-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-7,10,11,14-18,24-30 and 32-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's Amendment and Declaration filed on 10/27/2010.

- Claims 1, 6, 10-11, 24, 27-28, 34, 40 have been amended.
- Claims 1-2, 5-7, 10-11, 14-18, 24-30, 32-40 are pending in the instant application.

Declaration under 37 CFR 1.132

The Declaration under 37 CFR 1.132 filed on 10/27/2010 is insufficient to overcome the rejection of claims 1-2, 5-7, 10-11, 14-18, 24-30, 32-40 based Bockow (U.S. Patent No. 5,709,855) in view of Edwards (U.S. Patent No. 5,989,559), Herbert et al (Clinical Evaluation and Management of. Work-Related Carpal Tunnel Syndrome. American Jour of Industrial Med. 37:62-74 (2000)), Hirano *et al.* (U.S. Patent No. 5,869,087), Liebschutz (PCT Publication WO 02/22109 A2) and Applicant's Specification under 35 USC §103 as set forth in the last Office action and discussed below in the *Response to Argument* section.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2, 5-7, 10-11, 14-18, 24-30, 32-40 rejected under 35 U.S.C. 103(a) as being unpatentable over Bockow (U.S. Patent No. 5,709,855) in view of Edwards (U.S. Patent No. 5,989,559), Herbert et al (Clinical Evaluation and Management of. Work-Related Carpal Tunnel Syndrome. American Jour of Industrial Med. 37:62-74 (2000)), Hirano *et al*. (U.S. Patent No. 5,869,087), Liebschutz (PCT Publication WO 02/22109 A2) and Applicant's Specification **are maintained** for reasons of record in the previous office action filed on 05/27/2010 and as discussed below.

Note, although the references are silent about "at least one symptom, [such as pain], is ameliorated for a period of 1 week or longer, [such as 3 weeks or several weeks], following application of said topical patch NSAID formulation", it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See *Bristol-Myers Squibb Company v. Ben Venue Laboratories,* 58 USPQ2d 1508 (CAFC 2001). "It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable." *In re Woodruff*, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. *In re Baxter Travenol Labs*, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145. On this record, it is reasonable to conclude that the same patient is being administered the same active agent by the same mode of administration in the same amount in both the instant claims and the prior art reference. The fact that

Applicant may have discovered yet another beneficial effect from the method set forth in the prior art does not mean that they are entitled to receive a patent on that method. Thus, references combined teach, either expressly or inherently, each and every limitation of the instant claims.

Response to Arguments

Applicant argues that the declaration of Dr. Larry Caldwell under 37 C.F.R. §1.132 (hereinafter "the Declaration"), that provides evidence and statements demonstrating that the combined teaching of the cited references does not render the claimed method obvious. Specifically, in support of the contention that Edwards fails to teach or suggest the above claim element, the Declaration states, "nowhere in Example P does Edwards teach that the symptoms were ameliorated for an extended period of time, i.e., 1 week or longer. Just because Edwards' extract cream may give immediate relief of symptoms does not mean that the cream would work over an extended period of time, i.e., a period of 1 week or longer". As such, neither Bockow nor Edwards teaches or suggests the amelioration of at least one symptom associated with median nerve pressure for a period of 1 week or longer, as claimed. As Herbert is cited solely for use of oral NSAIDs in treatment of carpal tunnel syndrome; Hirano and Liebschutz are cited for teaching diclofenac patches; and the instant specification is cited for teaching a commercially available hydrogel adhesive patch; these references do not remedy the deficiency of Bockow and Edwards. As such, the combined teaching of the cited references fails to teach or suggest each and every element of the claims and

cannot render the claimed method obvious. Thus, the rejection may be withdrawn for this reason alone.

The Examiner finds this argument unpersuasive, because as discussed above, although the references are silent about "at least one symptom, [such as pain], is ameliorated for a period of 1 week or longer following application, [such as 3 weeks] of said topical patch NSAID formulation", it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See *Bristol-Myers Squibb Company v. Ben Venue Laboratories,* 58 USPQ2d 1508 (CAFC 2001). "It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable." *In re Woodruff*, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. *In re Baxter Travenol Labs*, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145. On this record, it is reasonable to conclude that the same patient is being administered the same active agent by the same mode of administration in the same amount in both the instant claims and the prior art reference. The fact that Applicant may have discovered yet another beneficial effect from the method set forth in the prior art does not mean that they are entitled to receive a patent on that method. Thus, references combined teach, either expressly or inherently, each and every limitation of the instant claims.

Applicant argues that as described in the Declaration, "Prior to the actual reduction to practice reported in the application, it was not at all certain that application

of a NSAID topical formulation would result in amelioration of at least one symptom associated with carpal tunnel syndrome/median nerve pressure, much less amelioration of the at least one symptom for a period of a week or longer."

The Examiner finds this argument unpersuasive, because the BOCKOW reference teaches treating carpal tunnel syndrome with a topical composition, wherein the HERBERT reference teaches that it is commonly know in the prior art to use NSAID to treat carpal tunnel syndrome. Thus, one skilled in the art would have more than reasonable expectation of success.

Applicant argues that that Edwards' cited example fails to support an anticipation of success in practicing the claimed method, for the reasons set forth below, as further evidenced by the Declaration of Dr. Larry Caldwell. Edwards teaches that elemicin is a likely active agent of the banana peel extract (see Table 3 and col. 5, lines 59-62). Elemicin is a known psychoactive compound1 that is partly responsible for the anticholinergic-like effects of raw nutmeg. Edwards' active agents have very different properties, elemicin is a psychoactive agent that blocks the neurotransmitter acetylcholine in the central and peripheral nervous systems. As such, elemicin has a completely different mechanism of action compared to an NSAID because it acts in the nervous system via blocking neurotransmitters rather than acting locally via inhibition of inflammation signaling pathways.

The Examiner finds this argument unpersuasive, because EDWARD is simply a secondary reference to show that it is commonly known in the prior art to apply topical medication on or near the loci or sites of pain. The NSAID topical drug is taught by the

primary reference BOCKOW, wherein the topical application of the medication on or near the loci or sites of pain is commonly known in the prior art as disclosed by EDWARD.

Applicant argues that Herbert, Hirano, Liebschutz also fail to provide any support for a predicted success in practicing the claimed method. The Examiner finds this argument unpersuasive, because as discussed above, the BOCKOW reference teaches treating carpal tunnel syndrome with a topical composition, wherein the HERBERT reference teaches that it is commonly know in the prior art to use NSAID to treat carpal tunnel syndrome. Thus, one skilled in the art would have more than reasonable expectation of success.

Applicant argues that amended Claim 38 is further distinguished over the combined teaching of the cited references for specifying that at least one symptom associated with median nerve pressure is ameliorated for a period of 3 weeks or longer following application of a NSAID formulation. As discussed above, nowhere does Edwards teach that the banana peel extract reduced symptoms in a subject over an extended period of time, much less for a period of 3 weeks or longer. As such, Edwards fails to teach or suggest the amelioration of at least one symptom for a period of 3 weeks or longer, as claimed. Furthermore, for the same reasons set forth above, one of ordinary skill in the art would not extrapolate the results obtained with Edwards' banana peel extract to a NSAID formulation. One would not predict success in ameliorating at least one symptom associated with median nerve pressure after application of a NSAID

formulation for any period of time, much less for a period of 3 weeks or longer, without actually performing experiments and obtaining positive results.

The Examiner finds this argument unpersuasive, because as discussed above, although the references are silent about "at least one symptom, [such as pain], is ameliorated for a period of 1 week or longer following application, [such as 3 weeks] of said topical patch NSAID formulation", it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See *Bristol-Myers Squibb Company v. Ben Venue Laboratories,* 58 USPQ2d 1508 (CAFC 2001). "It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable." *In re Woodruff*, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. *In re Baxter Travenol Labs*, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145. On this record, it is reasonable to conclude that the same patient is being administered the same active agent by the same mode of administration in the same amount in both the instant claims and the prior art reference. The fact that Applicant may have discovered yet another beneficial effect from the method set forth in the prior art does not mean that they are entitled to receive a patent on that method. Thus, references combined teach, either expressly or inherently, each and every limitation of the instant claims.

Applicant argues that amended Claim 39 is further distinguished over the combined teaching of the cited references for specifying that at least one symptom

associated with median nerve pressure is ameliorated for a period of several weeks or longer following application of a NSAID formulation.

The Examiner finds this argument unpersuasive, because as discussed above, although the references are silent about "at least one symptom, [such as pain], is ameliorated for a period of 1 week or longer following application, [such as 3 weeks or several weeks] of said topical patch NSAID formulation", it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See *Bristol-Myers Squibb Company v. Ben Venue Laboratories,* 58 USPQ2d 1508 (CAFC 2001). "It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable." *In re Woodruff*, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. *In re Baxter Travenol Labs*, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145. On this record, it is reasonable to conclude that the same patient is being administered the same active agent by the same mode of administration in the same amount in both the instant claims and the prior art reference. The fact that Applicant may have discovered yet another beneficial effect from the method set forth in the prior art does not mean that they are entitled to receive a patent on that method. Thus, references combined teach, either expressly or inherently, each and every limitation of the instant claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAKE M. VU whose telephone number is (571)272-8148. The examiner can normally be reached on Mon-Tue and Thu-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618